



## DRUG ALERT

### CLASS 2 MEDICINES RECALL

**Action Within 48 Hours**  
**Pharmacy/Wholesaler Level**

Date: 08 June 2020

EL (20)A/25

Our Ref: MDR 115-03/20

Dear Healthcare Professional,

### **Torbay Pharmaceuticals (for Veriton Pharma Ltd)**

**Epistatus (Midazolam) 10mg/mL Oromucosal  
Solution (Multi Dose Bottles)**

**Unlicensed Medicine -  
MS13079**

Batch Number	Expiry Date	Pack Size	First Distributed
191111C	31/11/2021	5mL in 30mL bottle	20/04/2020
200113C	31/01/2022	5mL in 30mL bottle	30/03/2020

Active Pharmaceutical Ingredient (Midazolam)

#### **Brief description of the problem**

Torbay Pharmaceuticals has informed us that the child-resistant container closure for Epistatus 10mg/mL Oromucosal Solution (Multi Dose Bottles) may be faulty and incorrectly engaged. The child resistant closure can potentially be removed without unscrewing the cap closure. Removal of an incorrectly engaged cap closure will result in the yellow tamper evident band not being retained on the neck of the bottle. It should be noted that this product is manufactured as an unlicensed special.

#### **Advice for healthcare professionals**

Healthcare professionals are advised to stop supplying the above products immediately and quarantine all remaining stock and return it to your supplier using your supplier's approved process.

#### **Further Information**

For stock control queries please contact Veriton Pharma Ltd., Telephone +44 (0)1932 690325 or email [info@veritonpharma.com](mailto:info@veritonpharma.com)

For any medical information enquires please contact Veriton Pharma Ltd., Telephone +44 (0)1932 690325 or email [info@veritonpharma.com](mailto:info@veritonpharma.com)

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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